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Padmashree Gehl Sampath[*]

Abstract

The year 2005 marks the end of transition period for many developing countries with competent pharmaceutical sectors that competed in supplying generic versions of patented drugs to LDCs before, thereby inducing price competition and enhancing access to medicines. In a post-2005 scenario, the critical issue is whether LDCs without adequate manufacturing capabilities can make use of compulsory licensing expeditiously to induce price competition and secure lower prices. This paper uses empirical evidence collected during a firm-level survey of the Indian pharmaceutical sector to generate evidence on emerging strategies of firms. It shows that the vigour of compulsory licensing as a price-leveraging instrument post-2005 is incumbent mainly on its economic feasibility. It shows that Indian firms view the market potential (in terms of market size and profits involved in such supply, especially if they have to make specific technological investments to produce the drug) of the mechanism much more severely than before, and may be less inclined to engage in such production if their commercial expectations are grossly unmet. The analysis assesses implications of emerging strategies of firms in the Indian pharmaceutical sector for access to medicines both domestically and internationally, and highlights the challenges involved.

Key words: **product patents, Indian pharmaceuticals, generics, access**

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1. Introduction

The recently released report of the Committee on Intellectual Property, Innovation and Health of the World Health Organisation (2006) urges developing countries to facilitate access to cheaper medicines by using creating national frameworks that enable the full use of their right to compulsory license the manufacture of pharmaceuticals (CIPIH, 2006, p. 139).[1]

The potential role of compulsory licensing in promoting access to medicines is replete with compelling issues. Within the highly contentious debate on the impact of the Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement) on public health, poor countries have claimed that product patents on pharmaceuticals will lead to higher drug prices and access to medicine issues. The experiences of countries like Brazil and South Africa in 1999 led to an emphasis on instruments such as parallel imports and compulsory licensing in order to ease these impacts.[2] A special weight was laid upon exercising the option of compulsory licensing within the TRIPS Agreement, or merely the threat of its use, as a price-leveraging instrument in developing countries. It was felt that this option allows national governments to impose the threat of price competition through the production of cheaper generic versions of patented drugs. To strengthen these means, the Doha Declaration on the TRIPS Agreement and Public Health, 2001 and the decision on the implementation of Paragraph 6 of the Doha Declaration, adopted by the WTO countries on 30 August 2003 have tried to further the means by which developing countries can export drugs through compulsory licenses to least developed countries (LDCs) that do not have adequate local manufacturing capacities.[3] The 30 August 2003 decision reflects the consensus of all WTO members to waive Articles (f) and (h) of Article 30 of the TRIPS Agreement, so that counties with inadequate manufacturing facilities could make use of the compulsory license provision, especially after 2005. The Decision that culminated as an amendment to the TRIPS Agreement, makes it clear that the obligation of a developing country to produce predominantly for the local market will be waived if the

importing country which is a least developed country/developing country seeking to import drugs manufactured under the said license satisfies the terms laid out by Paragraph 2 of the Decision. Paragraph 2 in turn, makes the compulsory license incumbent upon: (a) the lack of local capacity to manufacture; (b) a condition that the compulsory license issued by the exporting member will be only for the amount needed by the importing member; and, (c) a notification to the TRIPS council by the importing member for the grant of a license for a national emergency or other circumstances of extreme urgency or a case of public non-commercial use. This allows developing countries to export drugs through compulsory licenses to other least developed countries that cannot manufacture them locally.

It is not really a battle to win. There is no doubt that introduction of price competition through generic manufacturers is critical to ensure access to medicines.[4] The WHO has also highlighted the impact of generic competition on price reduction, especially in a multiple source setting (Creese and Quick, 2001). Price competition through generic manufacturers' also has a role to play in introducing differential pricing in the market for drugs like those for HIV/AIDS (Hammer, 2002, p. 902). But whereas these aspects make the case for compulsory licensing so compelling, in practice, several issues remain open. One is forced to question the feasibility of this solution against the fact that 01 January 2005 marked the end of the transition period granted by the Agreement on Trade Related Aspects of Intellectual Property Rights, 1995 (the TRIPS Agreement) to developing countries to comply with its provisions on pharmaceutical product patents. From this date onwards, pharmaceutical firms can obtain full scale patent protection on their products in major markets in developing countries, such as India, and also prevent local firms from manufacturing generic copies of their patented products. The introduction of product patent protection in countries such as India means that the firms in such developing countries which, in the past, offered strong price competition through the production of cheaper generic versions of drugs patented elsewhere, will now be able to produce them only through the 30 August 2003 solution. It remains to be seen how important this change will be, when compared to other factors affecting access to new medicines, especially for diseases that disproportionately affect India and other such countries.

1.1. The implications of the 30 August Mechanism in practice

To exploit the Doha Declaration and the 30 August 2003 Mechanism, not only should LDCs be able to take complete advantage of delaying patent protection on pharmaceuticals in their national frameworks, but LDCs without adequate manufacturing facilities should be able to use the mechanisms introduced by the 30 August 2003 mechanism to obtain supplies from India or a different developing country under a compulsory license *expeditiously*. In practice, the vigour of compulsory licensing as a price-leveraging instrument will be incumbent on two conditions: the economic feasibility of compulsory licensing and the legal apparatus required to put it into action. The condition of economic feasibility implies that if compulsory licenses do not make much economic sense for potential generic producers (in terms of market size and profits involved in such supply, especially if they have to make specific technological investments to produce the drug), it will drastically reduce the potential of this mechanism to serve as an instrument to induce price competition in the global market. As Grace (2003, p. 49) rightly identifies, the 30 August 2003 solution poses two pertinent economic issues for generic firms in a country like India:

(a) Does the compulsory license issued by an LDC serve as an economically feasible incentive for an Indian firm to invest in the development of a copy of the patented product?

(b) If the active pharmaceutical ingredients required for the product are not available easily, is the market large enough to attract the firm to invest in the production of active pharmaceutical ingredients?

The legal apparatus condition implies that the procedures spelt out for the grant of a compulsory license and the administrative costs imposed thereby should be minimal for it to be a powerful and easy-to-invoke option. However, the procedure spelt out under the 30 August 2003 decision is cumbersome. It not only spells out a lengthy legal process, but also places a substantial onus of administering the compulsory licenses on the TRIPS Council (Matthews, 2004). As a result, importing countries may have to face lengthy delays and costs associated with the administrative burden of

having to notify the WTO of their decision to use the mechanism and undergo scrutiny within the TRIPS Council before they can eventually proceed (Ibid, p. 97). Such procedural costs and delays also add to reduce its economic potential further.

This paper focuses on a critical aspect of the debate on access to medicines: the economic feasibility of the compulsory licensing solution post-2005 and its potential to act as a price-leveraging instrument in markets in developing and least developed countries, using India as an example. The paper analyses the impact of India's TRIPS compliance on emerging firm strategies for both R&D and business, in order to assess implications for both international and domestic access to medicines. The analysis is based entirely on primary data collected in a firm-level survey of the Indian pharmaceutical industry between October 2004 and January 2005. The paper is structured as follows. Section 2 analyses the main issues raised by India's TRIPS compliant product patent protection regime for access to medicines, namely: (a) which disease categories will be mostly affected? (b) what is the percentage of the drugs that will not be available for manufacture anymore and what implications does that have for public health? (c) what is the impact of these restrictions on manufacturing of generics on industry profits in a country like India? And (d) how will this affect industrial organisation and future trends, especially in relation to availability of generic drugs in major disease categories for LDCs? From section 3 onwards, the paper presents evidence gathered through the survey of the Indian industry on emerging firm strategies, industrial re-organisation trends, firm perceptions on economic feasibility of the compulsory licensing mechanism and the implications of these aspects on access to medicines in international and domestic markets. Section 6 contains the conclusions. It highlights the challenges involved in making compulsory licensing work to promote global public health.

1.2. Methodology

Several scholarly inquiries between 1995 and 2005 have tried to predict the impact of full-scale TRIPS compliance on the Indian market in general and strategies of Indian firms in particular (See for

example, Subramanian, 1995; Arvind, 1995; Lanjouw, 1998; Watal, 1999; Fink, 2000; Chaudhuri, Goldberg and Jia, 2004; and Grace, 2004). These studies have each examined various aspects of the patent landscape and its impact on the Indian industry using different methodological techniques, in order to predict the impact of product patent protection on the Indian pharmaceutical industry. In one of the earliest studies on the topic, Lanjouw (1998) analyses how the introduction of product patents for pharmaceuticals may benefit or adversely affect India. She bases her analysis on information obtained over a period of six months, September 1996-March 1997, in India through interviews with a wide range of people in the pharmaceutical sector. Through this and documents supplied by various pharmaceutical organizations and governmental agencies, she tries to predict whether one might expect or not expect to see changes occurring.

Fink (2000) examines the impact of patent protection on the behaviour of pharmaceutical multinationals and the market structure in India. His analytical approach builds around the calibration of a theoretical model to actual data from the Indian pharmacy market, to answer the hypothetical question of what the market structure would look like, if India allowed product patent protection on pharmaceuticals. He concludes that in case new on-patent drugs are newer varieties of off-patented products in the same therapeutic class, it will not have a large impact on prices of drugs. But if they are altogether new products, of which off-patent generic versions are not available, price rises associated with such products may be high (see p. 29). The model also shows that the simulated welfare losses for the Indian consumers were quite large (p. 30).

Grace (2004) and (2005) analyse the importance of pharmaceutical supplies from India and China for access to medicines on a global scale. She presents a review of the strengths, weaknesses, opportunities and responses of the Indian firms to changes in intellectual property protection, mainly the introduction of product patent protection. The analysis is largely based on secondary data supplemented with select interviews conducted with informants in order to confirm information taken from reports (Grace, 2004, p. 10).

Chaudhuri, Goldberg and Jia (2004) use detailed product-level data sets from India to conduct a case study of Quinolones in India, to show the potential adverse welfare effects of the TRIPS Agreement on the Indian industry. They estimate that "in the absence of any price regulation or compulsory licensing, the total welfare losses to the Indian economy from the withdrawal of the four domestic product groups in the fluoroquinolone sub-segment would be on the order of US$ 713 million, or about 118% of the entire systemic anti-bacterials segment in 2000" (p.1).

As opposed to these approaches, the data used in this paper was collected in a firm-level survey of the top 103 firms in the Indian pharmaceutical sector, ranked on the basis of their export potential, annual sales and R&D investment figures. The survey was conducted between October 2004 and January 2005. An innovation system-oriented and policy-relevant innovation survey at the firm level is complex and not too many such surveys have been conducted in the pharmaceutical sector in India. Firm level innovation surveys generally aim at gathering information on innovation inputs (both R&D and non-R&D oriented) and outputs (usually in terms of products or processes of innovation) (Smith, 2005, p. 161). Thus, firm level surveys incorporate the exploration of critical aspects of innovation, such as sources of innovative ideas, impetus to innovation, interactions between various actors in the innovation system, external inputs to innovation and so on (Ibid). A common weakness of earlier innovation surveys was that they were weakest in precisely the features of greatest utility: few innovation surveys carried out in the 1990s, for example, were consciously designed for policy-relevance (Oyelaran-Oyeyinka et al, 2004). To avoid this, the main focus in the firm level survey conducted for this study has been on learning and innovation processes in Indian pharmaceutical firms and how these will be affected by stronger intellectual property protection and not so much on innovation inputs and outputs. The information generated in the firm level survey is used to analyse emerging firm strategies, both for R&D and business, and their impact on access to medicines in India and other countries in Africa. While doing so, the study also seeks to generate evidence for several theoretical predictions made in earlier studies on introduction of product patent protection in India.

A background country report of the Indian pharmaceutical industry was first prepared to feed into the survey. A range of semi–structured interviews with experts in the area of pharmaceutical innovation and intellectual property rights were conducted as the second step in order to help clarify the structure and content of the survey and to provide content validation to the survey questionnaire. The questionnaire was then administered to the top 103 firms in an industry list created using data on export potential, R&D investments and annual sales from online databases on the Indian pharma sector, such as the *India Infoline* and *Pharmabiz*.

One of the key contributions of the survey in analysing emerging issues related to patent protection for pharmaceutical innovation and access to medicines in the Indian context is a categorization of firms in the Indian pharma sector into three main groups. This categorization, which was achieved on the basis of the country report and the empirical data collected, is very helpful in analysing emerging firm strategies and their implications in detail. The three groups are: large scale firms (both Indian and MNC-held), medium sized operators who are either generic producers or specialists in niche areas of contract research and small scale units which manufacture drugs for the bigger firms within India[5] and will be refereed to as group 1 firms, group 2 firms and group 3 firms for the purposes of analysis in this paper respectively. These three groups are representative of the Indian pharmaceutical sector, which although amounting to approximately 6000 firms in total, engaged in the production of both bulk drugs and formulations.[6] Since this categorization is corroborated by their export potential, ability to invest in R&D activities and annual turnover, it helps pin point the extreme variance in industry structure because it embodies the vast differences amongst firms in terms of firm size, employment capacity, innovation potential, R&D investments and exports. These differences condition strategies for R&D and business, and have implications for access to medicines in depth.[7] Out of the 103 firms surveyed as part of the empirical investigation, 31 belonged to group 1, 27 to group 2 and 44 to group.

2. The Indian pharmaceutical sector, product patents and access to medicines: can we predict the impact?

Indian pharmaceutical firms produce 22% of all generic drugs world-wide and also actively supply vaccines (Verma, 2005, p. 436).[8] The sector has witnessed exponential growth rates over the 1990s, growing on an average, at 15% for bulk drugs and 20% for formulations (IBEF and Ernst and Young, 2004a). The sector has an overall production value of US$ 10 billion, ranking 4th worldwide in production volume and 13th in value ((IBEF and Ernst and Young, 2004a, p. 8, Grace, 2005, p. 8).[9] Correspondingly, its export potential has also steadily been on the rise. As of 2005, 400 bulk drugs and almost all formulations that are sold worldwide were made in India (Grace, 2005, p. 8).

India's full scale compliance with the TRIPS Agreement proceeded in several stages up until 2005. The Patents (Amendment) Act, 1999 introduced the mail box system and set up a system of exclusive market rights (hereafter, EMRs) to be retrospective from 01 January 1995, in conformity with the TRIPS Agreement. The Patent (Amendment) Act, 2002 introduced 64 changes to the Patent Act of 1970, the most important ones of these being the extension of patent term from 14 to 20 years, and the reversal of burden of proof from patent holder to alleged infringer (see People's Commission, 2003). The final set of changes to make India's patent regime comply with the TRIPS Agreement *in toto* were first contained in the Indian Patent Ordinance of 2004, that has now been replaced by the Indian Patent (Amendments) Act of 2005.[10] These stipulations are a far cry from the earlier Indian Patent Act of 1970, which excluded product patent coverage for pharmaceutical products completely, and limited process patents to a period of seven years (or five years from the date of sealing of the patent, whichever was shorter).

India's full-scale TRIPS compliance raises several critical issues from an access to medicines perspective, namely; (a) which particular disease categories will be mostly affected? (b) what may be the percentage of the drugs that will not be available for manufacture anymore and what implications

does that have for public health? (c) What is the impact of these restrictions on manufacturing of generics on industry profits? And (d) how will this affect industrial organisation and future trends, as far as manufacture of generics for the poor of this world is concerned? Will firms shift their supply preferences and focus on developed countries instead?

The disease categories most likely to be affected are categories of drugs with a high speed of new product development due to emerging resistance, such as antibiotics and anti-infectives (e.g. ARVs, TB drugs, anti-malarials), and new drug classes such as those for cancer and diabetes which have little therapeutic competition/substitution (Grace, 2005, p.7). Since only newer, patented medicines will be effective in these categories; these will be unaffordable in developing countries. Yet, as Grace (2005) notes, the public health ramifications of product patent protection could be quite big, since many of these drugs are critical for diseases that affect the masses, such as HIV/AIDS and Malaria, and more importantly, several of the patented drugs are one component of a combination therapy. This implies that their price drastically affects the possibility of optimal treatment to millions world-wide.[11]

The Indian Patent Amendment Act, 2005 has gone some way in enabling the production of generics, especially in some of these very affected disease categories such as HIV/AIDS. The Indian Patent law excludes drugs which have patent priority dates prior to 1995 from its purview: these cannot be patented in India and hence generic production can continue. But for drugs patented between 1995 and 2005, the Act provides that these can still continue to be produced in return for payment of a "reasonable" royalty in case a generic firm within India has made "significant" investments (see Baker 2005). These stipulations are weak, and may be the subject of future litigation since aspects such as: what is a "significant" investment, what is the ceiling on the royalty rate that needs to be paid, are all not defined (see Baker, 2005).

Table 1: Implications of the patent (amendment) Act of 2005 on some HIV/AIDS drugs

Most antiretroviral therapies presently available for the treatment of HIV/AIDS are multiple drug combinations that require to be taken over a continued period of time. The presence of one patent-protected drug in a combination therapy therefore acts as a major hindrance to efforts to make the combination available at affordable prices. For example, GSK's patent on the drug 3TC effectively prevented the availability of the combination therapy of NVP, d4T and 3TC, which should otherwise have been the most affordable AIDS treatment worldwide. Despite such problems, there are several other combination therapies that will not be affected by the introduction of product patent regime in India.

The fixed dose combinations of Stavudine/ lamivudine/ nevaripine can continue to be produced since all these drugs have pre-1995 patents. In the case of Tenofovir, although the patent was issued in 1992, Gilead has a priority patent date for an ester/ salt of Tenofovir, Tenofovir Disoproxil Fumerate that has been granted in 1997. Cipla is presently manufacturing 'Tenvir', a version of Tenofovir Disoproxil Fumerate, which could be affected if Gilead is granted an Indian patent on the ester/ salt. Section 3 of the original Patent Act has been amended in the Patents Amendment Act of 2005 to exclude from patentability "salts, esters, polymorphs, metabolites….and other derivatives of known substance…unless they differ significantly in properties with regard to efficacy." Therefore, it remains to be seen if Gilead will be granted the patent for the esther. Cipla could potentially engage either in pre-grant opposition or challenge the grant on the basis of Section 3.

Combivir, on the other hand, contains two drugs that are pre-1995 – AZT and lamivudine. Both these drugs are not patentable in India since they are pre-1995. But GSK has a formulation patent on Combivir that was taken in 1997. Cipla took GlaxoSmithkline to court in the UK on grounds of "lack of novelty" for its patent on Combivir (GB2235627), which Cipla claimed was a combination of its earlier two ARV products, AZT (patent expiry date 2005) ands Lamivudin (patent expiry date 2007). Although Cipla won the case in the UK in 2004, GSK's patent on Combivir is currently in the

mailbox in India.

Source: Grace (2005), Gehl Sampath (2005).

On the question of industry profits, however, there is some evidence that the introduction of product patents will lead to significant losses to Indian firms, at least across some product segments. A recent study conducted by Choudhury, Goldberg and Jia (2004) uses detailed product-level data sets from India to conduct a case study of Quinolones in India to show potential adverse welfare effects of the TRIPS Agreement on the Indian industry. They estimate that "in the absence of any price regulation or compulsory licensing, the total welfare losses to the Indian economy from the withdrawal of the four domestic product groups in the fluoroquinolone sub-segment would be on the order of US$ 713 million, or about 118% of the entire systemic anti-bacterials segment in 2000" (p.1). More generally, Grace (2005, p. 17) concludes that between 10-15% of the Indian production will be affected by product patent protection. Working with 2005 estimates, which quote the industry's worth to be US$ 10 billion, this will imply that approximately US $1 billion to 1.5 billion is at stake.

How does all this affect industrial organisation and future trends for R&D and business within the Indian pharmaceutical sector? R&D investment has been steadily on the increase amongst Indian companies, and almost all company representatives interviewed from group 1 and 2 firms clearly indicated that their strategies for both R&D and business have been in a slow-but-steady transition over the past few years, in order to enable them to cope with India's TRIPS compliance and ensuing strong international competition (field interviews). According to estimates, investment in R&D by Indian firms has gone up from a total of US $80 million on R&D in the year 2001 to over US $ 170 million in 2004. Approximately 90% of all R&D investments come from group 1 companies, and by the year 2010, group 1 firms aim to invest 10% of their annual turnover into R&D (field interviews). These investments have also produced some results already: the number of drugs in Phase I and II trials have tripled from 5 in 2003 to 16 in 2005 (Grace, 2005, p. 8).

3. Patent protection and emerging trends amongst Indian firms[12]

The Indian pharmaceutical industry has come of age. Its major strengths include a cost-competitive manufacturing base that extends to clinical studies, extensive skills in chemistry and process development, ability to manufacture over 50% of the bulk drugs needed for its pharmaceutical production activities locally, the emergence of a promising biotechnology industry, availability of local scientists and R&D personnel of a high scientific quality and a wide network of organisations performing various aspects of pharmaceutical R&D (CII, 1999; IBEF and Ernst and Young, 2004a, p. 2; Grace, 2004, p.18). Despite these achievements, there are several aspects that call for urgent policy reform.

The lack of minimum good manufacturing practices applicable across the industry, and adequate regulatory enforcement of such standards is a major challenge facing the industry's reputation. In recent years, there have been several contrasting estimates on the extent of spurious/counterfeit drugs produced in and exported by the Indian pharmaceutical industry (see Nature, 2005). These estimates vary between 0.5% (as presented by State authorities within India) and 35% (ascribed to WHO studies).[13] Wary of the fact that such claims undermine the reputation industry as a whole, as a producer and exporter of quality drugs, the Indian government has taken several steps to remedy the issue, such as setting up an expert committee to review the situation, and the enactment of Schedule M of the Drugs and Cosmetic Act which is a regulatory initiative prescribing quality standards. The Expert Committee published its report in 2003, which contains a series of recommendations to deal with the issue.

There are other gaps in the innovation system that could critically affect the performance of the industry post-2005. These include the lack of patent-related training at universities, and large regulation gaps in very important areas such as clinical testing and biotechnology (Ramani, 2002). While India is being promoted heavily as a clinical outsourcing hub, there are several regulatory aspects that may thwart India's potential in clinical sciences. Apart from regulations preventing animal

testing within the country, that were until recently a big hindrance to Phase II clinical trials, the scientific and technological capabilities required for Phase II and III of clinical trials are very few and far between in the country.[14] Recent initiatives include the setting up of three centres for clinical research in the country by the global firm, Quintiles and also expansion of operations within Indian companies to include performance of clinical research on a contract basis, such as Clinigene by Biocon (Maria and Ramani, 2004). Other global majors, such as Eisai, have also opened three centres for clinical R&D in India (D'silva, 2005). But problems persist, including the lack of trained staff, bureaucratic processes to accredit trials and scandals regarding unauthorized drug trails on the people (Padma, 2005, p. 436). The government of India is in the course of taking action on several of these aspects that require immediate attention, and the impact of these changes in fostering innovation remains to be seen.

3.1. Emerging R&D and business strategies

Emerging strategies of Indian firms are therefore a natural response to an industrial and regulatory climate that still is not fully able to cater to the needs and concerns thrown up by tough international competition, and the losses induced by the restrictions placed on them by the new patent regime. They are a mix of both cooperative and competitive strategies, in order to adapt and capitalize on opportunities created by the new industrial environment. These emerging firm strategies portray a scenario that is very different from what was observed in several Latin American countries, where local firms mainly adopted cooperative strategies upon entry of foreign MNCs, thereby leading to vertical integration (as a result of acquisitions) and steep increases in drug prices. The behaviour of the Indian industry is more in keeping with what one would expect to see in an environment where a well-to-do local industry with clearly established areas of expertise is faced with strong international competition. Newer technologies and evolving market structures (in this case, as induced by the product patent regime and strong competition from global firms) almost always create new market segments and niches with many opportunities for specializations that the Indian industry is quick to capitalize upon, although this will also be accompanied by a high degree of consolidation in the industry in the coming years.

On the whole, each one of the three firm groups are using a combination of competitive and collaborative options to deal with pressures imposed by India's full scale TRIPS compliance. At the outset, three sets of predictive observations can be drawn on firm behaviour given the various pressures that the industry faces.

Table 2: Emerging firm strategies: a categorization[15]

Firm group	Drivers	R&D Strategies
Group 1	• Entry and establishment in regulated markets • Realization that gains of entry are higher than initial costs to overcome barriers to entry • Need to strengthen product portfolios to insure against greater global competition	• Greater investment into R&D through revenues earned by product sales in regulated markets • Higher innovation in generics, new products and processes and bulk drugs.
Group 2	• Taking advantage of business opportunities created by the shift in focus of group 1 companies to regulated markets • Need to strengthen competitive advantages, to make use of CRAM opportunities	• Active supply of off-patent generics to the semi-regulated and unregulated markets, by setting up manufacturing plants outside India or strengthening supplier partnerships • Focus on establishing themselves as niche players for contract research by choosing specific areas that give them competitive advantage: e.g., clinical research, domestic marketing. • Moving up the industry's value chain gradually.
Group 3	• Survival in the light of Schedule M of the Drugs and Cosmetics Act and India's full fledged TRIPS compliance	• Upgrading facilities to Schedule M standards in order to continue manufacturing for group 1 and 2 companies.

Source: WHO-INTECH survey conducted by author, 2005

Group 1 firms are keen on having their own intellectual property protection in order to establish themselves within India and other regulated markets worldwide, since they are capable of investing in R&D. These firms, which have a turnover of over 3000 crore rupees, perform two main kinds of pharmaceutical activity: generics production and innovative R&D. These two are overlapping, i.e., firms are venturing into innovative options of generic production such a specialty generics[16] and are also keenly developing their own marketing infrastructure within India and other regulated markets. The need to set up marketing infrastructure abroad has led to several international acquisitions and alliances by Indian firms in the EU and the USA in recent times. The experience of group 1 companies has been that while the entry barriers to regulated markets for the supply of generics are very high, the monetary returns and the ease of business that follows entry into these markets are both higher than in the semi-regulated and unregulated markets worldwide (Field interviews). Added profits earned by the sale of generic products in regulated markets make it possible for group 1 companies to make larger R&D investments. Group 1 companies in India are therefore choosing a mix of cooperative and competitive strategies to deal with challenges and opportunities post-2005.[17] Although most Indian companies clearly acknowledge that producing the next new blockbuster NCE (new chemical entity) in India is still some way off, most competitive strategies adopted by these companies are centred on enhancing their R&D focus. This includes the development of non-infringing processes, research on new chemical entities, generics and specialty generics for regulated markets, novel drug delivery systems and biopharmaceutical research (Interviews; IBEF and Ernst and Young, 2004a, p. 11). Cooperative strategies are predominantly focused on increasing internal technological competitiveness and higher revenues from greater sales in regulated markets by tapping the marketing networks of the non-Indian partners through collaborations. Some cooperative strategies are also geared towards helping MNCs use the marketing networks of Indian companies locally to market their products, in return for know-how or other desirable collaboration.

Group 2 companies, which have an annual turnover between 100-300 crore rupees and have little or no investment capabilities to indulge in R&D, will predictably, remain pure generic suppliers, or at best,

shift to niche activities in product development that involves minor modifications. Their main focus will be on specializing in order to make use of emerging opportunities for contract research and manufacturing (CRAM). Towards this end, group 2 companies are trying to establish themselves as niche players in contract research and manufacturing by choosing specific areas where they can be competitive. Those who are planning to remain pure generic manufacturers are trying to quickly move in and capture shares in the semi-regulated and unregulated markets world-wide since the group 1 firms are gradually moving out of these markets into regulated markets.

In group 3 companies (annual turnover below 100 crore rupees), contrary to popular misconceptions; it will mainly be the enactment of Schedule M of the Indian Drugs and Cosmetics Act on minimum Good Manufacturing Practices (GMPs) that will force unviable units to close down, as opposed to introduction of product patent protection. This segment of the industry will perhaps witness maximum consolidation in the next decade. Although many of the group 3 firms are also strategically aiming to benefit from contract manufacturing, either for larger Indian firms or even for foreign firms post-2005, only those who can upgrade their plants to at least to the GMP standards as contained in the Schedule M of the Drugs and Cosmetics Act will tend to benefit. Even such a generalization has to be made with a note of caution, since the standards contained in Schedule M of the Indian Drugs and Cosmetics Act are much below the WHO standards on GMPs. In this context, it remains unclear as to whether group 3 companies that do upgrade their facilities to the standards specified under Schedule M can indeed target to manufacturing for MNCs/ firms operating outside India. In order to be able to manufacture for foreign partners from regulated markets, standards of foreign inspectors such as USFDA will need to be met by group 3 firms, which are much more stringent than both the Indian and WHO standards on GMPs. It therefore seems more likely that most such companies which do adhere to GMP standards as specified by Schedule M will manufacture for group 2 companies in India who are looking at filling in the demand for generics in the unregulated and semi-regulated markets or foreign partners directly from the unregulated and semi-regulated markets. Alternatively, group 3 companies that comply with Schedule M will also supply to companies that are targeting the domestic

Indian market. Table 3 below contains an illustrative list of major competitive and cooperative strategies emerging in the Indian industry.

Table 3: Main competitive and cooperative strategies adopted by Indian firms

Competitive Strategy	Examples
Specialty generics	Several development initiatives at both Cipla and DRL are actively focusing on the development of specialty generics.
No infringing processes	Ranbaxy's non-infringing process on Cefuroxime Axetil enabled Ranbaxy to be its sole seller for almost one and a half years in the US market. Matrix Laboratories has developed its own non-infringing process on Citalopram and is the sole exporter of the API to Europe presently.
Novel drug delivery systems	Ranbaxy has licensed its NDDS on ciprofloxacin to Bayer AG that is under consideration in the USA right now. It is also actively involved in developing NDDS in several other therapeutic areas such as gastric retention.
New chemical entities	Ranbaxy licensed out its NCE RBx 2258 for the treatment of cancer to Schwarz Pharma AG. This NCE has now been dropped from clinical trials. Dr. Reddy's had licensed out its molecule for the treatment of Diabetes (Balaglitazone) to Novo Nordisk in 1997, for carrying out toxicology studies that form part of Phase II clinical trials. This molecule also had to be dropped from clinical trials due to toxicity issues.

Collaborative Strategy	Examples
In-licensing arrangements	Nicholas Parimal and Roche agreement on launching Roche's products dealing with cancer, epilepsy and AIDS in the local market (CII, 1999, p. 23). Agreement between Ranbaxy and K. S. Biomedix Ltd accords Ranbaxy exclusive marketing rights for TransMID, a biopharmaceutical product used in the treatment of brain cancer in India with an option to expand this to China and other South East Asian countries (IBEF and Ernst and Young, 2004b, p. 26). Agreement between Zydus Cadilla and Fermenta Biotech Ltd (A subsidiary of Duphar Interfran Ltd) that gives Zydus process technologies to manufacture Lisinopril and Benazepril exclusively within India.
Collaborative R&D	Glaxo SmithKline and Ranbaxy have a collaborative R&D arrangement for the development of new drugs in the areas of infective diseases and diabetes. Cipla has established an R&D deal with a smaller biotechnology firm, Avestagen Laboratories to produce the biogeneric drug for Artritis, *N-Bril*. Ranbaxy and Avestagen Laboratories have collaboration for the production of NCEs using biotechnological techniques. Avenstagen has collaboration with Astrazeneca Research Facility to help develop their TB Dots products.

Contract research	Biocon's subsidiary Syngene performs a large range of contract R&D activities for pharmaceutical firms world-wide Avestagen Laboratories, also a biotechnology firm, performs R&D for European pharmaceutical companies.

Source: Field interviews conducted by author, 2005; IBEF and Ernst and Young, 2004b

3.2. Patenting in the Indian industry

The impact of intellectual property rights on specific sectors in developing countries will differ from one country to another depending on its level of development (Mashelkar, 2005). A point that is often brushed aside despite its obvious importance is that a tougher patent regime has significant advantages for the Indian pharmaceutical sector, given the stage at which it has reached now. Patenting activities have clearly been on the rise in India, accompanied by a growing realization that it is a primary factor in leveraging global competition to their advantage. There are segments of the industry which are benefiting from it extensively. Matrix Laboratories is a good example of a firm that is clearly benefiting from India's compliance with the TRIPS Agreement (see Gehl Sampath, 2007 forthcoming).

According to Morel et al (2005), when the top 25 countries worldwide are ranked in order and analysed for all US patents issued where at least one inventor is from a given subject country, India ranked third highest (see Table 2, p.4). They further find that the number of US patents per GDP per capita in India is 0.912, second only to USA and Japan (ibid.). Despite this, since the Indian Patent Act of 1970 systematically under-emphasized the importance of patenting in the pharmaceutical sector, patenting is a relatively new phenomenon in the Indian pharmaceutical sector and there is a need to

enhance awareness regarding the implications and potential of patenting amongst a large number of smaller firms.

Emerging patenting strategies of Indian firms fall into two broad categories – positive patenting and defensive patenting. Most Indian firms that perform innovative R&D are presently following a mixed strategy of both positive and defensive patenting. Positive patenting refers to the patenting strategy where firms use the patent system to secure their own products that are presently based on NDDS or polymorphs or novel combinations in Indian and other markets. Cipla, for example, has filed for 166 patents world-wide, whereas Ranbaxy has the third largest ANDA filings in the USA for 2004 (Interviews). Other Indian companies like Dr. Reddy's Labs are also filing up to 15-20 ANDAs in the US market each year (IBEF and Ernst and Young, 2004a). At the same time, several firms are aggressively adopting defensive patenting strategies, where they apply for patents in order to prevent others from obstructing their R&D activities. Defensive patenting, as one company executive put it, is to ensure that "…someone else should not be able to stop us from developing our own processes" (Field interviews).

4. The compulsory licensing option: less or more of "pills for the poor"?

Sales from regulated markets have begun to account for a large share of total revenues of firms in group 1 of the sector – in 2005, the US market itself accounted for 32% of the total revenues of Dr. Reddys Laboratories and 42% in the case of Ranbaxy (Rangnekar, 2005). As highlighted in section 3, gearing up towards international competition has also meant that the three groups have invested on improving aspects that affect their competitiveness most, such as introduction of GMPs and receiving market exclusivity as "first-to-file" in the USA (Shalden, 2006; Gehl Sampath, 2005). But at the same time, the wave of industry consolidation and the emphasis on innovative R&D amongst firms that can upgrade their R&D and production facilities may have implications for access to medicines, because they are primarily motivated by the need to enhance competitiveness and not a public health vision.

4.1. The Legal framework for compulsory licensing

Section 92 (A) of the Indian Patent (Amendment) Act 2005 embodies the 30 August 2003 Decision and is meant to facilitate the Indian industry to continue supplying cheaper generic versions of patented drugs to those LDCs that do not have adequate domestic manufacturing capabilities. Section 92 (A) deals with compulsory licensing of pharmaceuticals for export purposes and reads as follows:

"Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India."

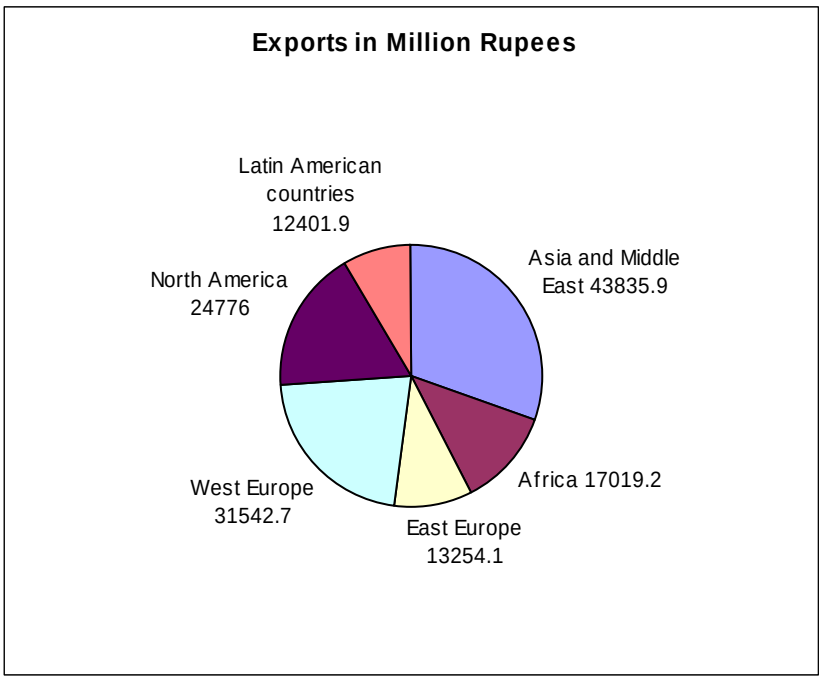
Exports are not unrestricted to such countries: they are only allowed to countries that have 'by notification or otherwise allowed importation of the patented pharmaceutical products from India'. The regime also provides for a three year period (starting from the date of patent approval) when the firms are not allowed to apply for a compulsory license. This requirement is much beyond what is stipulated under the TRIPS Agreement, and requires that firms wait for three years before applying for a compulsory license to produce the drug locally, except in cases of a 'government declared emergency' (Baker, 2005).

4.2. Industry consolidation, LDC exports and the economics of compulsory licensing

Figure 1 below contains the CHEMEXIL data for exports of the Indian industry as a whole to all regions world-wide. As the figure shows all of Africa accounted for only 17,019,2 million rupees in 2003-2004, whereas Europe and North America account for almost 50% of all exports; a trend that continued in 2005. The 103 firms that participated in the survey confirmed this skewed distribution further. Emerging business strategies amongst the 103 firms revealed that presently only 42 firms,

spread across all three groups export to Africa. Another 42 firms export to other Asian countries and these firms were once again as in the case of Africa, equally divided between all groups. In contrast, the 40 firms that were exporting only to the European Union and North America predominantly belonged to Groups 1 and 2.

Figure 1: Region-wise distribution of Indian pharmaceutical and chemical exports, 2003-2004 (Source: CHEMEXIL, 2004).



On the face of it, this distribution indicates that a large proportion of the firms surveyed belonging to all three groups are supplying to African countries and other least developed countries and developing countries until now. But it also is indicative of a gradual, on-going transition in the industry structure vis-à-vis supplies to African countries presently, which will continue well into the future. The emerging R&D and business strategies of Group 1 pharmaceutical firms are geared towards ensuring profitable returns for their products so that they can continue to make large scale investments in R&D and compete at the global level. This mandates that their R&D focus is on global diseases and business strategies target to enhance their entry into regulated markets. This marked movement of group 1 companies from the unregulated and semi-regulated markets to regulated markets will continue with group 1 firms tending to focus on getting a larger share of global regulated markets, and consequently giving secondary importance to semi-regulated and unregulated markets. Group 2 companies, on the other hand, will be quick to fill in the profitable opportunities that are being created by the shift of group 1 companies from unregulated to regulated markets. Some firms in Group 3 that are able to

substantially upgrade their production facilities will also make this transition and benefit from the possibility to export to semi-regulated and unregulated markets.

To be able to test the economic viability of the compulsory licensing option provided by the 30 August Decision, embodied by Section 92 (a) of the Indian Patent (Amendments) Act of 2005, each firm was asked whether Section 92 (A) of the Indian Patent Act constituted a favourable economic incentive for exports, especially to LDCs? Of the 103 firms, only 25 firms thought it was an economically lucrative option, whereas 78 firms did not think so. Of the 25 firms who answered in the positive, a group-wise classification reveals that only 6 belonged to Group 1, only 4 to Group 2 and notably, 15 firms belonged to firm Group 3. The common reason given by firms in groups 1 and 2 for not considering it a lucrative option was that India's TRIPS compliance increased the procedural hassles associated with such exports enormously, and that this was not worth their while, especially since the economic returns from such exports were very low. Group 2 firms also mentioned the constraints posed by the fact that their product range may be very different than those that might be in demand for imports by LDCs under such a license. These firms also expressed that the economic returns of investing in securing supplies of active pharmaceutical ingredients that are different from those that they normally require for their activities or investing into reverse engineering efforts and technological investments to produce the medicines will mostly not be profitable to them since it will be bound only to the said compulsory license.[18] A common reason quoted by the 15 firms of Group 3 which were willing to supply to LDCs under a compulsory license was that decreased competition for exports to LDCs will enable them to strengthen their export potential. Table 4 below contrasts the general exports of firms in all three groups to Africa until now versus firm perceptions on how many of them would still find it lucrative to supply under Section 92(A) of the Indian Patent (Amendments) Act, 2005, as generated by the survey. As mentioned before, 42 out of 103 firms surveyed export drugs to African countries presently: 15 of these are group 1 companies, 12 of these are group 2 companies and 15 were group 3 companies. But in response to the question whether they would still find it lucrative to supply generic versions of drugs patented in India post-2005 to African countries, not only did the total number of firms willing to consider the option reduce to 25 firms, the group-wise division changed drastically.

Table 4: Comparison between exports to Africa in 2004-2005 and export projections of firms under section 92(A) of the India's new patent regime

Firm Group	Present exports to Africa	Projections of future export intentions under sec. 92(A)
Group 1	15	6
Group 2	12	4
Group 3	15	15
Total	42	25

Source: WHO-INTECH survey conducted by author, 2005

At least three points are worth noting from these emerging business and R&D trends. Firms in groups 1 and 2 will most likely continue to supply under compulsory licenses to LDCs so long as these generic products are the same as those that they were manufacturing pre-2005,[19] although group 2 firms will generally be keener. If these are generic versions of products patented between 1995-2005, according to the Patent (Amendments) Act, the firms can continue to produce them if they have made significant investments already, subject to payment of a royalty amount to the patent holder: the prices may experience slight rises in keeping with the royalty rates. If there is a demand for generic versions of newly patented drugs (that is, products that were not being manufactured by Indian firms in generic versions until 2005), firms in Groups 1 and 2 may consider supplying the least developed countries market under compulsory licenses., so long as commercial considerations are taken into account, at least to some extent[20] In these cases, it has been suggested since long that LDCs will have a better chance with Group 1 companies in the case of newly patented drugs if they could aggregate demand regionally. A good example of this is the recent Clinton Foundation Initiative (see Table 6 below). Despite being keener, group 2 firms may be limited by process technologies and bulk drug requirements required, especially if the drugs in demand are very different from those that are being manufactured and exported by Group 2 firms to semi-regulated or unregulated markets normally.

Several Group 3 companies that answered in the positive are companies which have little or no experience in exporting pharmaceutical products mainly because they were not able to match up to competition from other Indian firms in Groups 1 and 2 before 2005. They see the export restrictions created by India's product patent protection as an opportunity to enter LDC markets. This may not be a very feasible option, since most of these companies do not have facilities that are GMP-compliant.

Table 5: The Clinton Foundation Initiative for HIV/AIDS Drugs

The Clinton Foundation reached a landmark agreement with eight pharmaceutical companies in January 2006, which will have the impact of drastically lowering the impact of AIDS tests and drugs worldwide. As part of the agreement, Cipla, Ranbaxy and Aspen Pharmacare (South Africa), all of which rely on Matrix Laboratories (also an India firm) for their active pharmaceutical ingredients supply, will offer the ARV Efavirenz for USD 240 and Cipla will also offer the ARV Abacavir for USD 447. Efavirenz and Abacavir are second line ARVs used by patients who have developed resistance to first line ARVS or have shown severe side-effects. The deal undercuts the already existing low-priced ARV drugs by a further price reduction of 30%. As part of the deal, companies in India, China and Israel will also offer AIDS tests to poor people in developing and least developed countries for a price ranging from 49 to 65 US dollar cents.

The reduction in drug prices of both Efavirenz and Abcavir were achieved by finding alternate (and cheaper) routes of sourcing the active pharmaceutical ingredients for their manufacture. Matrix Laboratories, which specializes in developing non-infringing propriety processes for the production of active pharmaceutical ingredients, now supplies the ingredient to manufacture Efavirenz at a very low price. Company co-operation in this instance was made easy due to the demand aggregation that the Clinton Foundation achieved: this offered profits large enough for a company like Matrix Labs despite the low rates for the ingredient. Mr. Nimmgadda Prasad, the Executive Chairman of Matrix Labs noted in this context: "They are really providing a very comprehensive assistance program and

are very sensitive to the commercial needs of the companies. Because the Clinton Foundation has 50 eligible countries in its purchasing consortium, it offered high enough volumes to justify lower margins."

The reaction of Matrix Labs is clearly demonstrative of the situation most Indian companies are in. They are keen to supply and will continue to do so, including by developing new or alternate processes, but would like the initiatives to be sensitive to their commercial needs as well. Earlier efforts by the Clinton Foundation to secure first-line ARVs from Indian companies in 2003 also evoked similar responses. Pranesh Choudhury, the spokesman for Ranbaxy shared with the press at that time, that Ranbaxy which sold 2.2. million USD worth of ARVS in 2002-2003, would profit from the deal because of the large quantities of drugs involved.

Source: Schoofs (2006), Agence France Presse (2003); Strides Press Release (12 January 2006).

5. Access to medicines in the local Indian market

Will product patent protection in India automatically increase the availability of new drugs within the local market? One of the first systematic studies on the topic shows that the grant of product patents is not a factor that directly affects whether new drugs are marketed in the country that grants such protection, and how quickly. The analysis covered a large sample of 68 countries at all income levels and includes all drug launches over the period 1982-2002, and found that the results on whether stronger patent protection leads to quicker product entry in middle and low income countries is mixed, with some evidence that in the short term, the chances that a strong patent regime leads to quicker product entry in countries that have good local facilities (Lanjouw, 2005, p. 24). In keeping with this finding, most executives from subsidiaries of large MNCs who were interviewed during the survey were very optimistic about the introduction of newly patented products in the Indian local market from 2005 onwards. But they made it conditional on the full-scale implementation of the Indian Patent (Amendments) Act of 2005 (field interviews).

Assuming that these drugs are in fact made available within the country, it is likely that the newly patented drugs will be expensive, at least in the therapeutic categories where there are no generics available to offer price competition (Fink, 2000). But the definition of patentability, as contained in the Indian Patent (Amendment) Act of 2005 and its effectiveness in dealing with "evergreening" will also play a very large role in determining the nature of competition that Indian firms will be able to put up in the generics market. The new Section 3 of the Indian Patents (Amendment) Act of 2005 now contains an explanation that was inserted specifically to deal with the problem of evergreening.[21] The explanation reads as follows: "For purposes of this clause, salts, esters, ethers, polymorphs, metabolites….shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy." A shortcoming though, is that it puts much of the onus to prevent evergreening on patent examiners (through pre-grant oppositions) and/or courts.

In other cases where there are indeed newly patented products with no generic price competition in a given therapeutic category, the critical question will be: how many Indian people will be able to access them? Even if one/some Indian firms create novel drug delivery systems or other novel applications for such drugs, it is not likely to be of much help if a foreign firm/ MNC holds the molecule patent.

Several other factors will also be critical in determining access to medicines for the Indian population in the mid-term or long-term, apart from product patent protection issues. Some of the main ones that require immediate attention in the Indian context are discussed here. Others, such as health infrastructure and distribution systems, availability of adequate financial resources, rational selection of medicines, are all very important but beyond the scope of this paper.

5.1. Competition law issues and compulsory licensing for the domestic Indian market

The provision of the original Indian Patent Act of 1970 that linked the grant of a compulsory license to "working a patent" locally has now been deleted in order to comply fully with the TRIPS Agreement.

Despite some of the other provisions in the Act that still preserve some of the old vigour of compulsory licensing, it remains to be seen how this will play out in practice. Indian administrative authorities, including the judiciary, have very little experience in dealing with patent-related issues and disputes. The global pharmaceutical industry, on the other hand, has proved to be fertile ground for anti-competitive practices many of which are promoted by accumulation of patents by firms, such as coercive bargaining, hold-up effects, and unfair terms in license agreements between firms that share research results (see for example, Correa, 2000). Although India has an enabling competition law framework in place, there is a lack of awareness of issues in intellectual property-competition policy interface that practices in the global pharmaceutical industry may give rise to. As a result, it is highly likely that post-2005, Indian competition enforcement agencies will be over-whelmed by the magnitude and diversity of competition law issues in the pharmaceutical sector. The grant of 'patent-like' rights in case of all patent applications between the date of publication and approval of patent is a provision in the present regime that can have severe consequences for competition (Baker, 2005, p. 2). It is especially likely that as a result of this provision, foreign firms will still make patent applications/ claims on salts/ esters/ polymorphs or other substances excluded from patentability, aimed at preserving their market share in the local market, at least for a short while.[22]: This leaves one clearly reminiscent of cases of false listings by pharmaceutical companies in US FDA's Orange Book, just so that generic entries by competitor firms can be delayed.[23]

In addition to such competition issues posed by the entry of global pharmaceutical players into the Indian industry, marketing practices within the Indian market itself are a cause for concern. Present pharmaceutical marketing culture in India creates a large potential for collision between medical representatives of pharmaceutical firms and doctors/ hospitals, in order to influence the brands of drugs that are prescribed. For several decades now, the general practice amongst Indian firms was to produce their drugs under brand names. Business strategies therefore, were mainly aimed at promoting brand names to consumers. Lanjouw (1998) notes, "… [e]arly entrants with strong brands seem to have a persistent advantage in the market." Since the market operated with immense product differentiation with each firm offering the same/similar product under a different brand name, and

since there is virtually no information for the consumer to differentiate amongst the various brands of the same products, quality control is through a firm's reputation and doctor's prescription of certain brands over others (field interviews).

This creates the scope for a typical vertical restraints problem that can only be dealt with by an efficient competition law framework. For example, Dr. Reddy's Laboratories holds a dominant market position for their Nimersulide brand Nice: the brand controls 70% of the market, a large part of the success being attributable to the presence of extensive brand marketing networks with thousands of sales representatives. Indian companies also indulge in giving large margins to retailers in order to promote their brands (Field interviews), and it is common practice that most of the large firms in group 1 have extensive brand marketing networks for their brands. Cipla, for example, has a sales force of around 2500 representatives within India (field interviews). Smaller firms that may have equally good products at competitive prices but no marketing infrastructure may end up with insufficient profits, due to the difficulties of marketing their products. The emerging cooperative in-licensing alliances between MNCs and large local firms need to be viewed against this reality. They may, in fact, help thwart competition from smaller firms within the Indian industry that do not have large marketing infrastructure, even within those therapeutic categories where generic price competition is possible. The costs of these practices, if they continue unabated, will eventually be borne by the uninformed consumer in the Indian market.[24] In an effort to eliminate price distortions that are caused by high retail trade margins in the sector, a decision of the government of India (dated 08 January 2005) has had the effect of bringing all drugs and medicines (other than traditional medicines) under the maximum-retail price based excise assessment. This has brought about an end to the earlier practice of levying excise duty on drugs on the ex-factory price, which meant that companies could make significant profits by selling drugs at prices that were much higher than the ex-factory price and thus offer significant margins to traders to promote their products (Nagendranath, 2005).

The dependence on the medical professionals to prescribe brands to patients goes beyond generic products. Since the normal practice amongst Indian doctors is to rely on drugs that are published in major British medical journals, like the Lancet, Indian firms fear the situation that when they do come up with completely new products, they may not be able to market them. A good example of this is Cipla's Kelfar, a new drug introduced in 1995 (See discussion in Chaudhuri, 2005, p. 18). This deferiprone drug was very hard to promote within India, although it was a good substitute for the only other deferiprone drug in the market, produced by Novartis at the time (ibid). According to Cipla's Managing Director, Dr. Hamied, drugs like Kelfar failed to capture the local market because of the reaction of Indian doctors (Pers. Comm, Dr. Hamied, 2005).

The usual practice amongst the Indian judiciary of referring to cases from USA and Europe to substantiate decisions will only exacerbate the situation and may go against the interests of the Indian industry and public health concerns. Over and above all this, India does not have a large number of qualified and experienced patent examiners. The lack of qualified patent examiners and the time lapse between the grant of a patent and its publication in the official Gazette that the industry can access are other issues that need immediate attention (field interviews).

5.2. Data exclusivity

There is a clear distinction between keeping information secret (data protection) and doing approvals and clinical work "relying" exclusively on the original patent holder's data submitted to obtain regulatory approval for the patented product (data exclusivity). Article 39(3) of the TRIPS Agreement places a requirement upon member countries to provide protection to regulatory data under specific circumstances. Data exclusivity, a relatively new form of protection, is one such form of protection and it refers to the protection of pharmaceutical registration files that contain data submitted by pharmaceutical companies to regulatory agencies, such as the US Food and Drug Administration and the European Agency for the Evaluation of Medicinal Products (EMEA), for the purposes of obtaining market approval of patented drugs (Pugatch, 2004). Grant of data exclusivity prevents generic

companies from using the test data submitted by the original patent holder to regulatory authorities to prove bioequivalence of the generic version of the products. In practice, data exclusivity terms, since they are granted from the date of introduction of a particular product in a given market, may have the effect of extending the monopoly term of the patent holder beyond the term of the patent and delaying the entry of generics.

There seems to be no clear economic justification as to why data exclusivity should be granted to firms that already avail a patent protection term of 20 years globally for their products. It has been argued that data exclusivity allows firms to rely on some form of protection when they introduce their products, especially since they cannot be sure whether all countries will grant effective patent protection. But this form of "back-up" protection mechanism seems to be unnecessary, especially since the TRIPS Agreement has circumscribed the ability of countries to deny patent protection under normal circumstances to a very large extent. Furthermore, in the light of recent evidence which suggests that strong levels of intellectual property protection may not have such a direct bearing on the decision of pharmaceutical companies as to when they introduce their products in different markets world-wide (Lanjouw, 2005), one wonders if data exclusivity can be defended on this basis. In fact, grant of data exclusivity terms seems to contravene principles of bioethics, since it forces generic manufacturers who wish to introduce generics before the expiry of data exclusivity periods to generate their own test data through the conduct of clinical trials. Furthermore, a reading of Article 39(3) of the TRIPS Agreement shows that although there is a requirement to provide protection to regulatory data under specific circumstances, it is not necessary that this protection is granted in the form of data exclusivity (Watal 2001; Correa, 2002; Chaudhuri, 2005). Article 39(3) gives countries the choice to countries to decide upon the form of protection.

India is presently under pressure from the USA to consider granting five year data exclusivity (Baker, 2005). Assuming hypothetically that a developing country like India granted data exclusivity of five years, this would mean the following in reality. A product for which a patent was granted in 1995 is valid until 2015. But if this product is introduced in the Indian market in 2013, then data exclusivity

in Indian law would protect the regulatory data submitted by the company until 2018 (5 years from introduction), thus delaying the entry of generics (and extending the product monopoly) by three more years than the twenty years granted under the patent. Generic firms will then have to reproduce costly trials to prove bioequivalence of the drug, without which they cannot obtain market approval for the drug even if they can legally produce it (Baker, 2005).

Such a *sui generis* regime of data exclusivity goes beyond what is provided by the TRIPS Agreement. India should clearly assess its impact on public health in terms of delayed entry of generics and wasted expenditure of Indian generic companies in duplicating costly trails before acceding to such demands on a bilateral level (CIPIH, 2006, p. 143-144, see recommendation 4.20).

5.3. Price control and its effectiveness post-2005

The Indian Drug Price Control Order was first introduced in 1970 and amended several times until recently when it was replaced by the National Pharmaceutical Pricing Policy of 2002. Price control has played a very important role in ensuring access to medicines. According to government authorities, rise in prices of medicines under price control is only around 1%, whereas medicines that are not under price control have had an average price rise of around 7% in the past decade (Pers Comm., G. S. Sandhu, 2005). Yet, there are several problems with price control and its scope as it is operating in India presently that undermines its effectiveness.

Previous experience with price control shows the acute trade-off between accessibility and affordability. Both local Indian companies and MNCs do not find the introduction of drugs in price-controlled categories lucrative. Therefore when price control was imposed on a particular drug, more often than not, they either discontinued its production or created other deviations. The Price Control Order relies mainly on ORG data to assess prices, which takes into account only retail prices.[25] Therefore, prices of drugs for very important diseases, such as HIV/ AIDS and Cancer, are left out of

the scope of the Order, since most of the drug supply in the case of these diseases is institutional (such as to hospitals) and escapes the economic criteria of the Order. The drug categories in the Order are completely out-dated. Although the criteria was meant to prevent cartels of drug manufacturers from exploiting consumers, the present Order relies on 1990 selection of drugs. As a result, Naproxyn, an analgesic is still under price control for several years now, although other analgesics, such as Ibuprofen and Diclofenac are not. The categories of illnesses listed in the Price Control Order are outdated, and does not contain any reference to neglected diseases. These need to be re-defined so that neglected diseases and other important health priorities get sufficient attention under the price control mechanism.

Lastly, the price control mechanism as it operates today, does not effectively control the prices of imported drugs. The practice under the Order for imported drugs had been to allow a margin over "landed" costs (cost of the drug/ active pharmaceutical ingredient when it lands on Indian territory). This practice has been problematic in the past because it is hard to monitor price collusions between any Indian importer and exporter of raw materials/drug. Previously, subsidiaries of MNCs operating within India have used this loophole to claim inflated prices for raw materials imported from their parental companies into India (Feinberg and Majumdar, 2001, p. 430). This problem will become much more acute from 2005 onwards, since patented products do not have to be produced locally.

For the price control mechanism to be effective to help in dealing with price rises accompanied with product patent protection in the local Indian market, these issues need to be eliminated. The government of India has constituted a Sandhu Committee that is looking into these matters in great detail. The aim of the committee is to reinforce accessibility of drugs in the post-2005 scenario by re-defining the categories and basis for price control (Pers. Comm., G. S. Sandhu).[26]

6. Conclusions

There is no doubt that intellectual property protection is not the only factor affecting access to medicines, but at the same time, consensus seems to be emerging on the fact that it can be an important one (see CIPIH report, 2006; Gehl Sampath, 2005; Grace 2005, among others). The foregoing analysis has focused on a very important impact aspect of the access to medicines debate: the reduced economic feasibility of the compulsory licensing solution post-2005 which directly affects its potential to act as a price-leveraging instrument in markets in developing and least developed countries. The focus has been on India's TRIPS compliance and emerging firm strategies for both R&D and business based on primary data collected during an industry-survey between October 2004-January 2005. The Indian industry is in a stage of consolidation not only due to the ratcheting up of intellectual property, but also due to India's new standards on good manufacturing practices (GMP) and the pressures imposed by dealing with loss of industry profits and increased foreign competition in the local and international markets at the same time. Emerging strategies of firms for both R&D and business are therefore mainly tuned in to protect themselves in this hostile climate and less tuned to access to medicines issues. In order to analyse this in-depth, the paper divided the pharmaceutical sector in India into three groups of firms, depending on their annual turnover, export potential and R&D investments. Some of its main findings are as follows.

India's full scale TRIPS compliance will only affect newer, patented medicines, especially those that are being patented post-2005. These will be very few, but the impact will be sizeable, since it will affect disease categories that show a high speed of new product development due to emerging resistance, such as antibiotics and anti-infectives (e.g. ARVs, TB drugs, anti-malarials), and new drug classes such as those for cancer and diabetes which have little therapeutic competition/substitution (Grace, 2005, p.7). These disease categories affect the masses world-wide, and lack of access to the state-of-the-art treatment in for such diseases will be a great loss.

Emerging strategies in the Indian pharmaceutical sector are not dictated by access to medicine concerns, as much as other commercial pressures. This is clear by the preference of groups 1 and 2 to move slowly into majorly supplying the regulated markets in order to increase profits. Innovation trends amongst the first two groups analysed by the author elsewhere (see Gehl Sampath, 2005) also show a large preference for global diseases in an effort to increase profits so that they can invest larger amounts into R&D.[27]

Although several firms presently supply to African countries from all the three groups, the results of survey clearly shows that the inclination to continue to supply under Section 92(A) of the Indian Patent (Amendments) Act of 2005 has declined. Firms repeatedly reiterated two main reasons for their decline in interest. The first reason is that the new regime increased procedural hassles associated with such exports enormously, and that this was not worth their while, especially since the economic returns from such exports were very low. Secondly, they expressed concern that constraints posed by the nature of demand: their product range may be very different than those that might be in demand for imports by LDCs under such a license. Firms expressed the concern that the economic returns of investing in securing supplies of active pharmaceutical ingredients that are different from those that they normally require for their activities or investing into reverse engineering efforts and/ or other forms of technological investments may not be profitable to them since it will be bound only to the said compulsory license. On the whole, although firms expressed their willingness to continue to supply, there is a marked transition in export trends away from such markets. The most significant change is that Indian firms (especially in groups 1 and 2) no longer view the production of generic versions of ***newly*** patented drugs (patented post 2005) as a profitable activity, since their ability to supply them to different markets and profit from increased sales is highly circumscribed by India's TRIPS-compliant regime. This does not mean that firms will not supply generic versions of important drugs; it only means that in future, efforts to induce them to produce a newly patented drug under a compulsory license may require parallel arrangements, such as regional aggregation of demand by countries which do not have significant manufacturing capabilities. The paper has given the example of the recent Clinton Foundation Initiative to make this point. Although the Indian Patent

(Amendment) Act, 2005 has gone some way in enabling the production of generics including those that have patent filing dates between 1995 and 2005, there are still numerous ambiguities in the legal regime. The stipulation under the new patent regime that bans the grant of a compulsory licensing in the first three years of a patent only exacerbates the situation on the access to medicines front.

Hence, the analysis in the paper leads us to make a preliminary conclusion that compulsory licensing in a TRIPS-compliant regime, as provided for by the 30 August 2003 decision will not have the same vigour as a price-leveraging instrument as in the pre-2005 scenario. This is in keeping with the findings of the recently released CIPIH report on the issue of compulsory licensing. The report notes that (p. 136): "Generic producers in both developed and developing countries argue that there remain economic and procedural barriers to their participation in these arrangements *(59, 60)*. Although their business models are different, generic companies share with the research-based industry the common motivation of serving the interests of their shareholders. The mechanism will not be used if the financial incentives for participation, taking account of the risks involved, are deemed inadequate. Whether this mechanism is capable of making supplies of lower cost drugs available to developing countries with inadequate manufacturing capacity remains to be seen. So far no developing country has sought to make use of it."[28] More research on this is needed to substantiate these results, so that it paves the way for timely and relevant policy action in international and national forums.

The paper has also some assessed other aspects that will affect access to medicines in both domestic and international markets. Whereas the grant of data exclusivity in India will affect both markets, factors such as India's competition policy and price control will predominantly shape public health considerations for the Indian population. India itself has the second largest population of HIV/ AIDS patients worldwide (Mitra, 2004; Shadlen, 2006), and therefore exploiting each option that enhances access to medicines to the fullest will be critical in the domestic context. Other interesting linkages between drug registration procedures, data protection, exclusive market rights and access to medicines, although important, have not been explored in this paper (Baker, 2004; Hill and Johnston, 2004; DFID/ HSRC, 2004).

Several problems on the demand side too are likely to affect the situation pervasively. To begin with, the state of patent laws in many African countries like Kenya and Malawi are already at the TRIPS-plus levels although these countries have the option of not complying to the TRIPS Agreement until 2016 (DFID/ HSRC, 2004, p. 7). Although since 2003, several developed countries (including Canada, the Netherlands, Norway) have amended their laws to allow for exports to countries with inadequate manufacturing facilities, no developing country has made use of CL option as provided for by the 30 August 2003 mechanism this far (CIPIH Report, 2006, p. 136). Experience with other countries in Africa that have used compulsory licensing to improve access to medicines before 2003 shows that they required most help in negotiating royalties (Pers. Comm., Jamie Love, 2005). Given the fact that the compulsory licensing mechanism as it stands now has substantial limitations due to its limited economic feasibility, one is forced to question whether LDCs can use this mechanism as a price leveraging instrument at all. Political pressures on LDCs also raise considerable scepticism as to whether countries may invoke this mechanism in the future, and to which extent. The watered-down economic potential of the instrument will only help patent holders' keenness to withhold their market positions and pricing levels.

In the light of all this, it may not take a long time until consensus gathers on the recommendation made on this point by the CIPIH: "The WTO decision agreed on 30 August 2003, for countries with inadequate manufacturing capacity, has not yet been used by any importing country. Its effectiveness needs to be kept under review and appropriate changes considered to achieve a workable solution, if necessary."[29]

7. References

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[1] Report of the Commission on Intellectual Property Rights, Innovation and Public Health, Public Health, Innovation and Intellectual Property Rights, WHO, Geneva, March 2006: hereafter referred to as CIPIH report in this paper.

[2] See the discussion on South Africa and some other cases in Ghanotakis (2004); Also see Matthews (2004); Lai (2001). For detailed discussions on the impact of compulsory licensing on price reduction of HIV/AIDS drugs in Brazil, see CIPIH Report (2006), Box 4.2 on p. 127-128; also see Rosenberg (2004).

[3] Article 31 (f) of TRIPS requires that a compulsory licensee supplies the domestic market predominately, hence preventing the grant of a compulsory license mainly to cater to export needs of another country.

[4] As opposed to attempts by the UNAIDS sponsored Accelerated Access Initiative (AAI), the main precursor to decisions by large MNCs to offer their HIV/ AIDS drugs at low prices in developing countries was a price war prompted by generic manufacturers like the Indian firm, Cipla. The announcement by Cipla that it will manufacture ARV cocktails for a price of 350USD and 600 USD for non-governmental organisations and governmental agencies respectively triggered off defensive price strategies by firms that held original patents on the ARVs (Pearl and Freedman, 2001). Cipla was joined by three other Indian firms, Hetero, Aurobindo and Ranbaxy in generic ARV supplies. For a detailed discussion on the factors that affected the success of the AAI, see Hammer (2002). Amongst other evidence on this issue, a study by Lucchini et al (2003) focussed on determinants of source prices of anti-retroviral drugs (ARVs) in Brazil and 13 African countries. On the basis of their surveys, Lucchini et al (2003, p. 201) note that: "Our results clearly show that introduction of generic substitutes is influential for price decrease and that patent protection in a country is associated with price increase."

[5] On the whole, the industry can be said to comprise of 100 firms belonging to group 1, 200 firms belonging to group 2 and 5700 firms to group 3 when one takes both formulations and active pharmaceutical ingredient work into account (Gehl Sampath, 2005, p. 27).

6 A recent expert committee set up by the government of India has clarified the number of active units on the basis of drug manufacturing licenses issued (Expert Committee, 2003, p. 3). According to the Committee, the total number of manufacturing units engaged in the production of both bulk drugs and formulations within India is not more than 5877. This can be further broken up into 1333 bulk drug units, 4534 formulation units, 134 large volume parenteral units and 56 vaccine-manufacturing units.

[7] For an analysis of the different "innovation modes" in the three groups of these firms, see Gehl Sampath, "Indian Pharma in Global Reach", TASM Special Issue, forthcoming (2007).

[8] The Indian vaccine market, estimated at approximately ~$150 million-260 million USD, accounted for 57% of the total Indian biopharmaceutical output in the year 2002-2003 (Srinivas, 2006).

[9] The IBEF (Indian Brand Equity Foundation) is a public-private partnership between the Ministry of Commerce, Government of India and the Confederation of Indian Industry (CII).

[10] Bare Act versions of the Patent Act, 1970 and all the subsequent amendments to the Act and Patent Rules analysed in this paper are available on the official website of the Government of India: http://www.patentoffice.nic.in/ipr/patent/patents.htm

11 See Grace (2005, p. 18) for an extensive discussion on this issue.

[12] This section is based on the analysis in Gehl Sampath, "Indian Pharma in Global Reach", TASM Special Issue, forthcoming (2007).

[13] Note that this figure was later invalidated when in response to a query by the Indian government, the WHO clarified that there is no WHO study that concludes that 35% of the world's spurious drugs are produced in India (Expert Committee Report, 2003).

[14] The NCE license agreement between Dr. Reddy's Laboratories and Schwarz AG (See Table 3) that has now been abandoned was in fact, for conducting Phase II and II clinical trials of the NCE only, since these facilities were not available within the country at that time (Field interviews conducted by the author with firm executives of Dr. Reddy Laboratories).

[15] Sridharan (2005) presents a similar categorization of the industry split into three main groups: the innovator, the collaborator and the endangered.

[16] Speciality generics are generics of reformulated older molecules, but made using new drug delivery

technologies.

[17] This is mainly applicable to the Indian firms in Group 1. The subsidiaries of MNCs that belong to this group are also planning to expand operations in the country or enter into collaborative arrangements but are waiting to see how well the Indian Patent (Amendments) Act, 2005 is implemented before implementing their course of action.

[18] Since a lot of new medicines encompass biopharmaceutical or other novel techniques, they may require technological investments and are also costly to reverse engineer (Grace, 2003).

[19] This can mean either pre-1995 molecules that are not covered by the TRIPS-compliant patent regime, or products that are generic versions of molecules patented between 1995-2005, but local firms can show that they have invested significantly into building such generic production activities and thus get exempted, as Indian Patent (Amendments) Act of 2005 provides.

[20] Some group 1 firms, notably Cipla, are extremely dedicated to continue producing generics of newly patented products. Cipla is the largest producer of generic drugs in India with around 800 products in the market in 2005 (field interviews). It has several R&D deals to continue with generic production of newer drugs, such as the collaborative agreement with a smaller Indian biotechnology firm, Avestagen Laboratories to produce the biogeneric drug for Artritis, N-Bril.

[21] Evergreening is a process through which the original patent holder firm can delay the entry of generics upon the entry of the patent. Common evergreening tactics include applying for patents on slight modifications of the drugs (salts, esthers, polymorphs, among others) or applying for recombination patents (drugs that simply combine two earlier drugs into one dose/ tablet) or even apply for a patent on very basic changes like a different dosage route.

[22] The Glivec case which is being contested by Natco Laboratories, Hyderabad is an example of this problem. The Natco brand Veenat 100 Imatinib is priced at Rs. 10,800 as opposed to Glivec's price of $3600 for 100 capsules.

[23] Under US law, a listing delays FDA approval of a generic product by 30 days. See Lancet (2002) for a discussion of the case where Bristol-Myers Squibb was charged with falsely listing a patent claim for Buspirone in the US FDA's orange book in order to delay generic entry.

[24] A 2002 study conducted by VOICE and NPPA (National Pharmaceutical Pricing Authority of India) on the availability and prices of medicines in India found that more than 60% of the patients consult chemists rather than doctors to decide which medicines to buy (See VOICE and NPPA, 2002).

[25] ORG-MARG is India's premium market surveillance and consulting firm, whose audits provide detailed product-level information based on monthly retail sales.

[26] In this context, an amendment to Schedule H of the Drugs and Cosmetics Act has also recently been enacted.

[27] See Gehl Sampath (2005), p. 53-54.

[28] Footnotes 59 and 60 read as follows: Koen, J. Canadian Generic Industry, Ottawa, CIPIH Country Visit, October 2004 and Proposal of the Regulation of the European Parliament and of the Council on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products to Countries with Health Problems, Brussels, EGA Position Paper, March 2005.

[29] See recommendation 4.15 on p. 139 of the report.